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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,875	10/12/2000	Michifumi Tanga	TANGA2	5274

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/29/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,875

Applicant(s)

TANGA ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.


Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 1-11, 13-16 and 22-25 in Paper No. 16 is acknowledged. The traversal is on the grounds(s) that restriction is only required when examination of all groups would be undue burden to examine. Applicant further argues that because Claim 12 has already been searched, there would be no substantial burden on the examiner to search Group II along with the claims of Group I. The instant claims are restricted under PCT rule 13.1 in accordance with 37 C.F.R. 1.499. The standard for restriction under rule 13.1 is "unity of invention" and not "undue burden" as Applicant argues. Therefore, Applicant's argument is irrelevant regarding the instant Restriction Requirement.

 § 1.499 Unity of invention during the national stage. If the examiner finds that a national stage application lacks unity of invention under §1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under § 1.143 and 1.144.

However, if "undue burden" was the standard for Restriction under 37 C.F.R. 1.4999, the argument would not be found persuasive because it is maintained that undue burden would be required to examine the claims of Groups II along with claims of Group I as evidenced by the fact that the claims of Group II have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of inventions II. Specifically, a search of the subject matter of invention I encompasses an extensive search of the solid state substrate art comprising substrate materials and substrate modifications. Conversely, a search of the subject matter of invention II is encompasses an extensive search of the DNA immobilization and DNA amplification art comprising reagents and conditions for immobilization and amplification. In response to Applicant's argument regarding the previous

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examiner's search of the subject matter of Claim 12, the argument is not found persuasive because Claim 12 has been amended to include additional limitations i.e. a polar radical group "selected from the group consisting ofand thio radical". Because these additional limitations have been added, any previous search of Claim 12 did not encompass these additional limitations. Therefore, instant Claim 12 has not been searched by the current or previous examiner.

For the reasons given above, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-11, 13-16 and 22-25 are currently under prosecution.

Previous Rejections

2. The previous rejections in the Office Action of Paper No. 10 are withdrawn in view of the amendments and new grounds for rejection. Applicant's arguments have been considered but are deemed moot in view of the withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed below.

Specification

3. The substitute specification filed 9 October 2001 has not been entered because it does not conform to 37 CFR 1.125(b) because the submitted substitute specification does not include a marked-up copy of the specification as required by section (2) below.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the

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amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Information Disclosure Statement

4. The references listed on the 1449 received 9 August 2000 have been reviewed and considered. Additionally, the references cited in the International Search Report have been reviewed and considered.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-5, 9-11, 13-16 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Chrisey et al (U.S. Patent No. 5,688,742, issued 18 November 1997) as defined by Sumiya et al (U.S. Patent No. 5,332,629, issued 26 July 1994).

Regarding Claim 1, Chrisey et al disclose a solid state substrate for DNA immobilization (i.e. diamond) (Column 7, lines 24-28), wherein said substrate has a thermal

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conductivity ration of at least $0.1\text{W}/\text{cm}^\circ\text{K}$ as defined by Sumiya et al (Column 1, Table 1) and wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27).

The recitation “for amplifying DNA” in the preamble of Claim 1 and the recitation “for amplifying and immobilizing DNA” in lines 3-4 of Claim 1 are recitations of intended use for the claimed substrate. The courts have stated that a claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). The intended use of the claimed substrate does not differentiate the claimed apparatus over the substrate of Chrisey et al.

Regarding Claim 2, Chrisey et al disclose said substrate is diamond (Column 7, lines 24-28).

Regarding Claim 3, Chrisey et al disclose said substrate is chemically modified (Column 7, lines 35-50).

Regarding Claim 4, Chrisey et al disclose said substrate has a polar radical at a terminal on the surface of the substrate (Column 7, lines 35-50 and Fig. 4-5).

Regarding Claim 5, Chrisey et al disclose said substrate wherein said polar radical is hydroxyl radical, epoxy radical or amino radical (Column 7, lines 35-50).

Regarding Claim 9, Chrisey et al disclose said substrate wherein said polar radical is an epoxy radical and said epoxy radical is introduced to a surface of said substrate with a silane coupling agent (Column 7, lines 41-43).

Regarding Claim 10, Chrisey et al disclose said substrate wherein said polar radical is an amino radical and said amino radical is introduced to a surface of said substrate with a silane coupling agent (Column 7, lines 45-51).

Regarding Claim 11, Chrisey et al disclose said chip wherein DNA is immobilized to said substrate (Column 3, lines 20-25 and Column 7, lines 21-28).

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Regarding Claim 13, Chrisey et al disclose a solid state substrate having DNA immobilized thereon wherein said substrate is diamond and is chemically modified (Column 7, lines 21-50).

Regarding Claim 14, Chrisey et al disclose said substrate having DNA immobilized thereon wherein said substrate has a polar radical at a terminal of the surface of the substrate (Column 7, lines 41-50).

Regarding Claim 15, Chrisey et al disclose said substrate wherein said polar radical is hydroxyl radical, epoxy radical or amino radical (Column 7, lines 35-50).

Regarding Claim 16, Chrisey et al disclose a chip for amplifying and immobilizing DNA (Column 9, lines 9-27).

The recitation “for amplifying and immobilizing DNA” is functional language and does not describe the claimed substrate in terms of structure. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114). Because “for amplifying and immobilizing DNA” does not describe structural components of the claimed substrate, the recitation does not distinguish the substrate over the prior art substrate.

Regarding Claim 25, Chrisey et al disclose the substrate of Claim 15 wherein said polar radical is an epoxy radical and said epoxy radical is introduced to a surface of said substrate with a silane coupling agent (Column 7, lines 41-43).

Response to Arguments

7. Applicant's arguments have been considered but are deemed moot in view of the withdrawn rejections and new grounds for rejection. However, the arguments are discussed as they apply to the above rejection.

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Applicant argues that while the Chrisey substrate is similar to that of the instantly claimed substrate, the processes of chemical modification of the substrates differ. Applicant argues that Chrisey does not disclose or suggest use of chemical modification by binding a chloride or a hydroxyl radical to the substrate. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., binding a chloride or a hydroxyl radical to the substrate) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims are drawn to a product i.e. a solid state substrate. In some embodiments, the substrate has a polar radical e.g. hydroxyl, carboxyl, epoxy or amino radicals. However, the claims are not drawn to methods for making the substrate. Hence, the claims recite method steps for making the substrate. Applicant's arguments address method steps for making the substrate i.e. binding a chloride or a hydroxyl radical to the substrate. Because the claims are drawn to the substrate and not the method of making the substrate, Applicant's arguments regarding the method of making the substrate are irrelevant to the instant claims.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114).

Applicant argues that while Chrisey teaches the substrate has a polar radical at the terminal, the polar radical is connected to the surface with a silane coupling agent or through an ester linkage. Applicant argues that Chrisey does not teach a carboxyl radical is connected to the surface of a substrate through an ester or amide linkage wherein the carboxyl radical is connected to the surface of the substrate with a silane coupling agent, a titanium coupling agent or an aluminum coupling agent. The argument has been considered but is irrelevant to the above rejection because Claims 6-8 and 22-24 which recite the limitation "carboxyl radical" is not rejected under 35 U.S.C. 102 as anticipated by Chrisey.

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8. Claims 1- 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Kobashi (U.S. Patent No. 5,777,372, issued 7 July 1998) as defined by Sumiya et al (U.S. Patent No. 5,332,629, issued 26 July 1994).

Regarding Claim 1, Kobashi discloses a solid state substrate (i.e. diamond) (Column 4, lines 30-39), wherein said substrate has a thermal conductivity ration of at least $0.1\text{W/cm}^\circ\text{K}$ as defined by Sumiya et al (Column 1, Table 1) and wherein said substrate is used for immobilizing biomolecules (Column 4, lines 41-48).

The recitation “for amplifying DNA” in the preamble of Claim 1 and the recitation “for amplifying and immobilizing DNA” in lines 3-4 of Claim 1 are recitations of intended use of the claimed substrate. The courts have stated that a claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). The intended use of the claimed substrate does not differentiate the claimed apparatus over the substrate of Kobashi.

Regarding Claim 2, Kobashi discloses said substrate is diamond (Column 4, lines 30-39 and 64-67).

Regarding Claim 3, Kobashi discloses said substrate is chemically modified (Column 10, line 63-Column 11, line 11).

Regarding Claim 4, Kobashi discloses said substrate has a polar radical at a terminal on the surface of the substrate (Column 11, lines 4-11).

Regarding Claim 5, Kobashi discloses said substrate wherein said polar radical is hydroxyl radical, carboxyl radical, epoxy radical or amino radical (Column 11, lines 4-11).

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 6-8 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisey et al (U.S. Patent No. 5,688,642, issued 18 November 1997) in view of Kobashi (U.S. Patent No. 5,77,372, issued 7 July 1998).

Regarding Claims 6-8 and 22-24, Chrisey et al teach a solid state substrate for DNA immobilization (i.e. diamond) (Column 7, lines 24-28), wherein said substrate has a thermal conductivity ration of at least 0.1W/cm ° K as defined by Sumiya et al (Column 1, Table 1) wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27) wherein said substrate is diamond (Column 7, lines 24-28) wherein said substrate is chemically modified (Column 7, lines 35-50) wherein said substrate has a polar radical at a terminal on the surface of the substrate (Column 7, lines 35-50 and Fig. 4-5) and wherein said polar radical is hydroxyl radical, epoxy radical or amino radical wherein the polar radical is connected on a surface through an ester linkage, an amide linkage or introduced with a silane

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coupling agent (Column 7, lines 35-50) but they do not teach said polar radical is a carboxyl radical. However, Kobashi teaches a similar a solid state substrate wherein said substrate is chemically modified to have a polar radical at a terminal wherein the polar radical is selected from the group consisting of hydroxyl, carboxyl, epoxy and amino (Column 10, line 63-Column 11, line 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the chemical modification of substrates as taught by Chrisey et al by chemically modifying with a carboxyl radical as taught by Kobashi based on the teaching of Kobashi wherein hydroxyl, carboxyl, epoxy and amino radicals function equally as chemical modifiers for diamond surfaces (Column 11, lines 4-11). The courts have stated with regard to chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). Therefore, one of skill in the art would be motivated to chemically modify the substrate of Chrisey et al with a carboxyl radical based on the similar chemical and physical properties of polar radicals taught by Kobashi (Column 10, line 63-Column 11, line 11) because one skilled in the art would have expected the carboxyl radical to function in an equivalent manner. Additionally, the skilled practitioner would have been motivated to the diamond substrate of Chrisey et al with a carboxyl radical based on the teaching of Kobashi wherein a biomolecule is immobilized via carboxyl radical-modification of diamond substrate (Kobashi, Column 10, line 63-Column 11, line 11).

11. Claims 6-10 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobashi (U.S. Patent No. 5,777,372, issued 7 July 1998) in view of Chrisey et al (U.S. Patent No. 5,688,642, issued 18 November 1997).

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Regarding Claims 6-10 and 22-25, Kobashi teaches a solid state substrate (i.e. diamond) (Column 4, lines 30-39) wherein said substrate is used for immobilizing biomolecules (Column 4, lines 41-48) wherein said substrate is diamond (Column 4, lines 30-39 and 64-67) wherein said substrate is chemically modified (Column 10, line 63-Column 11, line 11) wherein said substrate has a polar radical at a terminal on the surface of the substrate (Column 11, lines 4-11) and wherein said polar radical is hydroxyl radical, carboxyl radical, epoxy radical or amino radical (Column 11, lines 4-11) but they are silent regarding the connection of the radicals to the surface of the substrate. Chrisey et al teach a similar solid state substrate for DNA immobilization (i.e. diamond) (Column 7, lines 24-28), wherein said substrate has a thermal conductivity ration of at least $0.1\text{W}/\text{cm}^{\circ}\text{K}$ as defined by Sumiya et al (Column 1, Table 1) wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27) wherein said substrate is diamond (Column 7, lines 24-28) wherein said substrate is chemically modified (Column 7, lines 35-50) wherein said substrate has a polar radical at a terminal on the surface of the substrate (Column 7, lines 35-50 and Fig. 4-5) and wherein said polar radical is hydroxyl radical, epoxy radical or amino radical and they teach said polar radicals are connected on a surface through an ester linkage, an amide linkage or introduced with a silane coupling agent (Column 7, lines 35-50). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the method for connecting the polar radicals taught by Chrisey et al to thereby connect the polar radicals of Kobashi through an ester linkage, an amide linkage or through a silane coupling agent because Chrisey et al specifically teach their connections facilitate covalent immobilization of DNA to a substrate (Column 7, line 65-Column 8, line 13). Therefore, one skilled in the art would have been motivated to connect polar radicals to the substrate of Kobashi via ester, amide or silane coupling agent for the expected benefit of facilitating covalent attachment of biomolecules to the substrate as taught by Chrisey et al (Column 7, line 65-Column 8, line 13).

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Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
March 14, 2002